REMARKS

Claims 4-9, 11, 13-16, 18-26, 28-32 and 34-60 are in the present application.

Claims 19, 30 and 34 have been amended to clarify that the tablets made using the present invention are intended for administration to and dissolution on moist tissue surfaces other than those of the respiratory and gastrointestinal systems. Further, new claims have been added to specify that those moist tissue surfaces are buccal, tongue, eye or wound surfaces, and particularly buccal surfaces. Antecedent basis for these amendments and new claims is found in the present application at page 1, line 15 et seq.; page 3, lines 1-12; and page 24, line 20 through page 25, line 2. In addition, claims 19, 30 and 34 have been amended to clarify that in the formation of the fiber mats, and hence the tablets, of the present invention, the fibers and mats are formed so as to be integral with the active ingredient. Antecedent basis for this amendment is found in the present application at page 10, line 28 et seq. Finally, claims 55 through 60 have been added to the present application to specifically define the embodiment described in Figure 5 of the present application (antecedent basis found at Figure 5 and page 21, line 16–page 22, line 11).

The Examiner has continued and made final his rejection of claims 4-9, 11-16 and 18-48, under 35 U.S.C. § 103(a), based on WO 98/03267 (Coffee), in view of U.S. Patent 4,197,289 (Sturzenegger et al.) and U.S. Patent 5,320,855 (Roche et al.). The Examiner contends that Coffee teaches electrohydrodynamic processes and apparatuses to form fibers, fibrils, webs and mats, and Sturzenegger et al. teaches making pharmaceutical dosage forms by depositing an active material onto a web and cutting the web into individual dosages. The Examiner then contends that it would have been obvious to use Coffee's disclosed electrohydrodynamic process to make the webs described in Sturzenegger et al. The Roche et al. patent is cited merely to teach the use of saccharine and peppermint flavorings in pharmaceutical dosage forms. For the reasons given below, and in light of the amendments made to the claims herein, this rejection is respectfully traversed.

Before considering this rejection in detail, the present invention will be briefly summarized. The present invention relates to an efficient and effective method for manufacturing

a dissolvable tablet, e.g., a pharmaceutical tablet. These tablets are designed for administration directly to moist tissue surfaces other than those found in the respiratory and gastrointestinal systems. Specifically, these tablets are used for delivery of pharmaceuticals to the tongue, eye or wound surfaces, and particularly for buccal delivery in the mouth (i.e., on the tongue). In this method, a dissolvable carrier material is placed into an electric field so as to cause the formation of fibers or fibrils of the carrier. These fibers/fibrils then deposit on a support surface to form a web or mat. An active ingredient, such as a pharmaceutically active material, is incorporated into the mat or web as part of the formation process, and the mat or web is then formed into tablets. Preferred dissolvable carriers for use in this process include biodissolvable carriers, such as gelatin, starch, cellulose, cellulose derivatives, water-soluble polymers, polyvinyl pyrrolidone, polyvinyl alcohol, polysucrose, and sugar. The tablets formed and the apparatus for carrying out this process are also claimed. As amended herein, the active ingredient is at least partially coated with the fibers or fibrils in the tablet and, thus, the active material is an integral part of the mat/tablet itself.

The Coffee application, cited by the Examiner, teaches electrohydrodynamic (EHD) spray techniques to form solid or gel particles, as well as fibers or fibrils. These materials are taught to be of particular use for deposition onto the skin. The application, at page 17, teaches the particular adaptability of these fibers/materials for use in a wound dressing in that they cover the wound, are lightweight, and allow air circulation around the wound. The Coffee reference teaches delivery of active materials to the respiratory system and the gastrointestinal system of the patient. The claims of the present application, as amended herein, by contrast, teach the delivery of the active ingredient to moist tissue surfaces <u>other than</u> those of the <u>respiratory or gastrointestinal</u> systems. Of particular note, are claims 50, 52, 54 and 57 which are directed particularly to the use of the present invention for <u>buccal delivery</u>. Buccal delivery is not suggested in the Coffee reference. The Coffee reference focuses on delivery to the respiratory system and the gastrointestinal system, or use as a wound dressing. The present application, in fact, teaches away from gastrointestinal delivery due to the harsh nature of the environment

present there. Further, Coffee does not teach an important additional aspect of the present invention, i.e., the production of tablets from a mat formed from EHD fibers or fibrils.

To attempt to remedy this deficiency, the Examiner has cited the Sturzenegger et al. patent. The Sturzenegger et al. patent describes a method for forming solid dosage forms from a web. The web is formed using standard techniques from the paper- or film-forming industries. There is absolutely no suggestion to form the web using EHD or any other electrostatic spray technique. The web formed in Sturzenegger et al. is more like a continuous sheet or membrane, not an open web as formed in the present process. Moreover, Sturzenegger et al. seems to indicate, at column 11, lines 21-33, that holes in the web are defects. This would teach away from the open web formed by the EHD process of the present invention. Since, Sturzenegger et al. does not want a web with holes in it, he would not use EHD which inherently forms an open web. In the present invention, holes or openings in the pills formed are not defects, but rather are desired to encourage quick dissolution. Once the web is formed, Sturzenegger et al. teach that the active material is then deposited onto the surface of the already-formed web; an electrostatic powder spray is disclosed as one way this can be done. Thus, the materials formed in Sturzenegger et al. comprise a web having a coating of an active material on it. The claims of the present invention, as amended herein, require that the active ingredient be at least partially coated by the fibers or fibrils as they are being formed and thus the active ingredient is integral to the web itself, not merely a coating as in the Sturzenegger et al. patent. The Sturzenegger et al. patent does not suggest such an integral mixture of the active ingredient and the web material formed.

The Roche et al. patent does nothing to supplement the deficiencies of either the Coffee or the Sturzenegger et al. references. Roche et al. merely teaches the use of flavorants, such as saccharine or peppermint, in oral pharmaceutical dosage forms. The fact that saccharine or peppermint or other flavorants is known for use in pharmaceutical dosage forms is in no way disputed by the applicants herein. The Roche et al. patent does nothing to suggest the use of EHD or any other electrostatic spray technique to form a mat which is then formed into oral dosage tablets.

The claims of the present application require that the method of forming tablets, the tablets formed and the apparatus used for forming the tablets be adapted such that the tablets formed dissolve on introduction to a moist (non-respiratory, non-gastrointestinal) tissue surface, such as a buccal surface. This is not taught or suggested in either the Coffee or Sturzenegger et al. references. In fact, Coffee teaches delivery to the gastrointestinal and respiratory tracts. None of the cited references teach buccal delivery. Further, the claims of the present application require that the active ingredient be integral to the web formed, i.e., at least partially coated by the fiber or web as it is formed. Again Sturzenegger et al. teaches the full formation of the web and then the coating onto that finished web of the active ingredient, in sharp contrast to the claims of the present application. Accordingly, the claims, as amended herein, are not disclosed or suggested by either the Coffee, the Sturzenegger et al. or the Roche et al. references.

In light of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. § 103(a) is not applicable to the claims currently pending in the present application. Accordingly, it is respectfully requested that the rejection be withdrawn.

In light of the foregoing, reconsideration and allowance of the claims currently pending in the present application are earnestly solicited.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 this 26 day of July, 2004.

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Respectfully submitted,

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